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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/537,118	03/29/2000	Harry Dugger III	PHCO3.0-008	7521

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EXAMINER
HAGHIGHATIAN, MINA

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 07/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/537,118	DUGGER, HARRY	
	Examiner	Art Unit	
	Mina Haghighatian	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *26-34,37,38,53-61 and 79* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26-34, 37-38, 53-61 and 79* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The receipt of the Request For Reconsideration and amendments filed April 08, 2004 is acknowledged. Claims 35-36 are deleted and no new claims are added.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 26, 30, 33, 37, 53, 56, 58-60 and 79 rejected under 35 U.S.C. 103(a) as being unpatentable over Kanios et al (5,719197).

Kanios teaches compositions and methods for topical administration of pharmaceutically active agents. Topical administration means a direct contact of the formulation with tissue, such as skin or membrane, particularly the oral or **buccal mucosa** (col. 1, lines 29-59).

Kanios discloses that the composition comprises a therapeutically effective amount of at least one pharmaceutically active agent, a pharmaceutically acceptable solvent for the active agent (col. 2, lines 22-28). The solvent is preferably a polyhydric alcohol such as polypropylene glycol, ethylene glycol, also solvents such as fatty acids such as oleic acid, as well as fatty esters or alcohols. The solvent is present in an amount from about 20 to 50 weight percent based on the total weight of the composition (col. 4, lines 1-49). The concentration of the solubilized active agent can range from 1 and 50% by weight (col. 8, lines 1-9). The acceptable carrier is intended to be any

suitable finite or non-finite carrier including liquids, semi-liquids or solid carriers. Thus the active agent may be admixed with carriers such as spray-solution or any non-finite carrier known in the art for delivery of active agents (col. 8, lines 54-67; col. 9, lines 19-27). Other additives may be incorporated into the formulations such as flavorings (col. 10, lines 48-56).

Kanios discloses that pharmaceutically active agents suitable for such formulation include narcotic analgesics, hormones, antihistamines, antibiotics such as erythromycin, antinauseants such as ondansetron, antiulceratives such as cimetidine, immunosuppressants such as cyclosporine, benzodiazepines, clozepaine, etc (cols. 12-31).

Kanios does not exemplify a buccal spray formulation, however it does clearly teach that the formulations may be in the form of a spray solution for administering to the oral mucosa and thus to one of ordinary skill in the art, forming a buccal spray containing an active agent and a solvent, would be a logical extension of the disclosure of Kanios.

Claim 27-29, 31-32, 34, 38, 54-55, 57 and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kanios et al (5,719,197) as applied to claims 26, 30, 33, 37, 53, 56, 58-60 and 79 above, and further in view of Singer et al (5,364,616).

Kanios, discussed above, lacks specific disclosure on the concentration range and examples of the flavoring agent.

Singer teaches methods for prevention or treatment of gingivitis or periodontitis comprising topical administration to oral cavity, a composition comprising a safe and effective amount of a selective histamine-2 receptor antagonist compound, and oral care compositions used thereof. Compositions comprise about 0.001 to about 20% of a H-2 antagonist such as cimetidine, about 2 to about 99% of an oral carrier and about 0.04 to about 2% of flavoring agent by weight. The suitable carriers include ethanol, water and polyhydric alcohols such as glycerin, polyethylene glycol and propylene glycol. Suitable flavoring agents include menthol, oil of wintergreen, oil of peppermint, oil of clove, etc (col. 15-17).

Singer discloses that the said compositions, suitably in the form of a mouthspray, may optionally include other ingredients such as other active agents including antibiotics, anti-inflammatories, vitamins and minerals (col. 18-19).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made, given the general teachings on the topical (oral) spray formulations of Kanios to look in the art for relative and suitable concentration range and examples of the flavoring agent with the reasonable expectations of preparing an oral formulation that is acceptable and tolerable by patients, since flavoring is an important aspect of oral formulations.

Response to Arguments

Applicant's arguments filed April 08, 2004 have been fully considered but they are not persuasive.

Applicant argues that Kanios is teaching compositions and methods for the topical administration of active agents to a mammal, in particular, anesthesia and local anesthetic agents.

Applicant states that Kanios describes its compositions as "flexible, finite, bioadhesive compositions for topical application", defining finite as non-spreading. Applicant is correct in stating that the invention of Kanios is essentially about topical application by a flexible or adhesive composition. However, it is stated that preferred embodiments do not teach away from a broader disclosure. See *In re Susi*. As mentioned in previous Responses and Office Actions, Kanios is teaching other forms of compositions including liquid sprays. Applicants attention is drawn to column 9, lines 19-27, where Kanios recites "For example, in ONE embodiment, the anesthetic agents are dissolved in a solvent.....and then added to an adhesive .In ANOTHER embodiment, the resulting mixture is in cream, gel...., spray solution or other non-finite composition....". Also in column 10, lines 57-65, Kanios discloses that ".....when a non-finite carrier such as an ointment, gel, lotion...or spray-solution is used".

It is further noted that the instant claims are "composition" claims, and the product's properties are considered inherent. Therefor if Kanios is disclosing a formulation containing the same ingredients as the instant claims are reciting, then it is taken that both formulations will be absorbed systemically once administered to the oral

mucosa. It is also noted that "for transmucosal absorption" is considered intended use and is not given weight during examination.

Kanios, therefor, teaches the formulations and the method of administration.

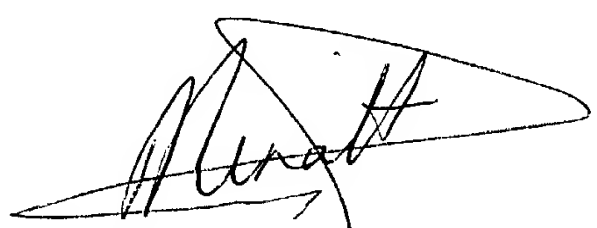
With regards to Singer's reference, Applicant argues that the formulations of Singer do not remedy the deficiencies in Kanios. The reasoning is that Kanios is disclosing a finite composition and not a sprayable solution. As mentioned above, Kanios does disclose solutions for spraying and teaches mucosa absorption and application.

Applicant argues that that there is no motivation to combine the disclosures of Kanios and Singer. Kanios is clearly teaching a spray solution formulation containing an active, a solvent and an additive such as flavoring agent, which may be administered to the oral mucosa. Singer is teaching formulations in a spray solution form which include an active, a solvent and a flavoring agent such as oil of peppermint, and discloses suitable concentration ranges for the flavoring agents. Clearly one of ordinary skill in the art, given the formulations of Kanios would be motivated to look in the art for specific flavoring agents and a suitable concentration range because both formulations are sprayed in the oral cavity and flavor in such formulations is an important factor in patient compliance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is 571-272-0615. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary L. Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Mina Haghighatian
Examiner
Art Unit 1616
July 06, 2004